



[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive Patent License: Antibody-Based Therapeutics and Chimeric Antigen Receptors Targeting Glypican-2

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Cancer Institute (NCI), National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive, sublicensable patent license to Stanford University, (“Stanford”), a non-profit university located in California, in its rights to the inventions and patents listed in the Supplementary Information section of this notice.

DATES: Only written comments and/or applications for a license which are received by the NCI Technology Transfer Center **[INSERT DATE 15 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]** will be considered.

ADDRESSES: Requests for copies of the patent applications, inquiries, and comments relating to the contemplated exclusive patent license should be directed to: Rose M. Freel, Ph.D., Senior Licensing and Patenting Manager, NCI Technology Transfer Center, 8490 Progress Drive, Suite 400, Frederick MD 21701 (for business mail), Telephone: (301)624-8775; Facsimile: (301)631-3027; E-mail: rose.freel@nih.gov.

SUPPLEMENTARY INFORMATION: The following and all continuing U.S. and foreign patents/patent applications thereof are the intellectual properties to be licensed under the prospective agreement to Stanford: United States Provisional Patent

Application No. 62/844,695, filed May 7, 2019 and entitled “CHIMERIC ANTIGEN RECEPTORS TARGETING GLYCIPAN-2” [HHS Reference No. E-064-2019/0-US-01].

The patent rights in these inventions have been assigned to the Government of the United States of America, Stanford University, and Children’s Hospital of Philadelphia. The prospective patent license will be for the purpose of consolidating the patent rights to Stanford, one of the co-owners of said rights, for commercial development and marketing. Consolidation of these co-owned rights is intended to expedite development of the invention, consistent with the goals of the Bayh-Dole Act codified as 35 USC §200-212.

The prospective patent license will be worldwide, exclusive, and may be limited to those fields of use commensurate in scope with the patent rights. It will be sublicensable, and any sublicenses granted by Stanford will be subject to the provisions of 37 CFR Part 401 and 404.

The invention pertains to novel antibody binders and chimeric antigen receptors (CARs) that target glypican-2 (GPC-2), a cell surface heparin sulfate proteoglycan with very restricted expression in normal tissue but with expression on many hard-to-treat pediatric and adult solid tumors such as glioblastoma, small cell lung cancer, uterine carcinoma, neuroblastoma, and medulloblastoma. Based on current available data, the intended use for the invention is as a therapeutic for the treatment of GPC-2 expressing solid tumors.

This notice is made pursuant to 35 U.S.C. §209 and 37 CFR Part 404. The prospective exclusive patent license will include terms for the sharing of royalty income

with NCI from commercial sublicenses of the patent rights and may be granted unless within fifteen (15) days from the date of this published notice the NCI receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. §209 and 37 CFR Part 404.

Complete applications for a license that are timely filed in response to this notice will be treated as objections to the grant of the contemplated exclusive patent license. In response to this Notice, the public may file comments or objections. Comments and objections, other than those in the form of a license application, will not be treated confidentially, and may be made publicly available.

License applications submitted in response to this Notice will be presumed to contain business confidential information and any release of information from these license applications will be made only as required and upon a request under the *Freedom of Information Act*, 5 U.S.C §552.

Dated: January 15, 2020.

Richard U. Rodriguez,

Associate Director,

Technology Transfer Center,

National Cancer Institute.

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